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510(k) K101546
Summary
for the
Endoform™ Dermal Template

1. SUBMITTER/510(K) HOLDER

JUN 2 3 2010

Mesynthes Ltd
69 Gracefield Road
Lower Hutt
Wellington
New Zealand 5010

Contact Person Brian Ward
Telephone: (+64 4) 931-3275

Date Prepared: June 17, 2010

2. DEVICE NAME

Proprietary Name: Endoform™ Dermal Template
Common/Usual Name: Extracellular matrix wound care product
Classification: Unclassified

3. PREDICATE DEVICES

- Endoform™ Dermal Template (Mesynthes) (K092096)

4. DEVICE DESCRIPTION

The Endoform™ Dermal Template is a wound care device comprised of one or two layers of ovine extracellular matrix and is supplied as a sterile perforated or non perforated sheet ranging in size up to 400 cm^2.

5. INTENDED USE

Endoform™ Dermal Template is supplied sterile and is intended for single use in the treatment of the following wounds:

- partial and full-thickness wounds
- pressure ulcers
- venous ulcers

- diabetic ulcers
- chronic vascular ulcers
- tunneled/undermined wounds
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The substantial equivalence of this device was established based on a declaration of conformity to design control requirements and on an assessment of the effects of the changes to the predicate device based on a risk assessment. As such, the Endoform™ Dermal Template (K101546) is substantially equivalent to the predicate device with respect to material composition, device characteristics and intended use.

7. PERFORMANCE TESTING

The Endoform™ Dermal Template (K092096) has been subjected to extensive non-clinical testing to assess the biocompatibility and the performance of the device. Endoform™ Dermal Template (K092096) was shown to be safe and effective as a wound care product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 23 2010

Mesynthes
% Medical Device Consultants, Inc.
Ms. Mary McNamara
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K101546
Trade/Device Name: Endoform™ Dermal Template
Product Code: KGN
Dated: June 2, 2010
Received: June 3, 2010

Dear Ms. McNamara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K101546

Device Name: Endoform™ Dermal Template

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Prescription Use _X_ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101546